

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of the Claims:

Claim 1 (presently amended): A method for the treatment, prophylaxis, or reduction of the risk of developing a menopause disorder in a human female mammalian subject in need thereof, comprising:

- (a) orally administering about 0.2 mg to about 50.0 mg of methyltestosterone ~~or an enantiomer, isomer, prodrug, or salt of methyltestosterone~~; and
- (b) percutaneously administering about 0.1 mg to about ~~100.0~~ 10.0 mg of estradiol ~~or an enantiomer, isomer, prodrug, or salt of estradiol~~ to a selected area or skin of the subject.

Claim 2 (canceled)

Claim 3 (previously presented): The method of claim 1, wherein the methyltestosterone is administered in the form of a tablet, capsule, cachet, lozenge, dispensable powder, granule, solution, suspension, emulsion or liquid.

Claims 4-7 (canceled)

Claim 8 (presently amended): The method of claim 1, wherein ~~the~~ about 0.1 mg to about 1.0 mg estradiol ~~or an enantiomer, isomer, prodrug, or salt of estradiol~~ is administered percutaneously.

Claim 9 (currently amended): The method of claim 8, wherein the estradiol ~~or an enantiomer, isomer, prodrug, or salt of estradiol~~ is administered in the form of a hydroalcoholic gel.

Claim 10 (original): The method of claim 9, wherein the hydroalcoholic gel further comprises at least one of a lower alcohol, a penetration enhancer, and a thickener.

Claim 11 (original): The method of claim 10, wherein the lower alcohol is selected from the group consisting ethanol, 2-propanol, and mixtures thereof.

Claim 12 (canceled).

Claim 13 (previously presented): The method of claim 10, wherein the thickener is polyacrylic acid.

Claim 14 (presently amended): The method of claim 1, wherein the estradiol ~~or an enantiomer, isomer, prodrug, or salt of estradiol~~ is administered as a percutaneous gel formulation, the formulation comprising:

(a) about 0.06% to about 10.0% estradiol ~~or an enantiomer, isomer, prodrug, or salt of estradiol~~;

(b) about 0.1% to about 5.0% polyacrylic acid;

(c) about 0.1% to about 5.0% triethanolamine;

(d) about 30.0% to about 98.0% ethanol; and

(e) water in an amount sufficient to make the formulation 100%,

wherein the percentages of components are weight to weight of the formulation.

Claims 15-19 (canceled)

Claim 20 (previously presented): The method of claim 1, wherein the methyltestosterone ~~or an enantiomer, isomer, prodrug, or salt of methyltestosterone~~ and the estradiol ~~or an enantiomer, isomer, prodrug, or salt of estradiol~~ are each provided as a separate component of a kit.

Claim 21 (canceled).

Claim 22 (presently amended): The method of claim 1, wherein the methyltestosterone or ~~an enantiomer, isomer, prodrug, or salt of methyltestosterone~~ and the estradiol ~~or an enantiomer, isomer, prodrug, or salt of estradiol~~ are administered in a sequential manner.

Claim 23 (presently amended): The method of claim 1, wherein the methyltestosterone or ~~an enantiomer, isomer, prodrug, or salt of methyltestosterone~~ and the estradiol ~~or an enantiomer, isomer, prodrug, or salt of estradiol~~ are administered in a substantially simultaneous manner.

Claims 24-73 (canceled)